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Please find below and/or attached an Office communication concerning this application or proceeding.

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# BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/086,253 Filing Date: March 01, 2002

Appellant(s): RINCAVAGE ET AL.

Philip Freedman Reg. No. 24,163 For Appellant

**EXAMINER'S ANSWER** 

This is in response to the appeal brief filed 11 October 2010 appealing from the Office action mailed 27 April 2010.

# (1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

## (2) Related Appeals and Interferences

The following are the related appeals, interferences, and judicial proceedings known to the examiner which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal:

This case was previously appealed to the Board of Appeals. The appeal was docketed as Appeal 2009-004309 and was decided 2 September 2009.

#### (3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

Claims 21-40 are finally rejected and pending.

#### (4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

## (5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

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# (6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

No rejections have been withdrawn and no new grounds of rejection have been entered since the Final Rejection mailed 27 April 2010.

# (7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

# (8) Evidence Relied Upon

2004/0107117	Denny	6-2004
20030074225	Borsand et al.	4-2003
2001/0047281	Keresman, III et al.	11-2001

## (9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

[1] Claims 21-22, 27-30, 31-32, and 37-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Denny (United States Patent Application Publication #2004/0107117) in view of Borsand et al. (United States Patent Application Publication #2003/0074225).

As per claim 21, Denny discloses a prescription fulfillment method, comprising; entering an unfilled prescription prescribed by a physician or medical service provider into a processing center wherein the prescribed prescription comprises at least medication brand or dosage (Denny; paragraphs [0010] [0027] [0030] [0031] [0064]); retrieving an unfilled prescription from the processing center (Denny; paragraphs [0011] [0012] [0032] [0035] [0036] [0064]); filling the prescribed prescription by a pharmacist (Denny; paragraphs [0031] [0032] [0036] [0049] [0063] [0064]), wherein the filled prescription is different from the retrieved prescription in respect of at least one of medical brand and dosage; entering the filled prescription into the processing center in fulfillment of the prescribed prescription for review by the prescribing physician or medical service provider (Denny; paragraphs [0031] [0032] [0036] [0049] [0063] [0064]).

While Denny provides for the pharmacist inputting information representative or indicative of a prescription to be filled (Denny; paragraph [0035]) and subsequently provides for the pharmacist inputting a code indicating that a prescription has been filled into the host system (Denny; paragraph [0041]), Denny fails to specifically indicate that the pharmacist enters filled prescription data that includes pharmaceutical type, quantity, cost or other information and "wherein the filled prescription is different from the retrieved prescription in respect of at least one or medical brand and dosage..".

However, as is evidenced by Borsand et al., it is well known in the prescription fulfillment art for the pharmacist to record or enter into a database, information regarding the specifics of a filled prescription including cost, drug type, and quantity administered to the patient. Accordingly, Borsand et al. teach a method wherein said filled prescription data includes information for said presented pharmaceutical type and said presented quantity and "wherein the filled prescription is different from the retrieved prescription in respect of at least one or medical brand and dosage..".

(Borsand et al.; paragraphs [0005] [0040] [0056] [0064] [0086] [0118] \*see electronic representation of filled prescription).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the teachings of Denny with those of Borsand et al. Such combination would have resulted in a system and method that enabled the entry of prescription information including prescribed drug and dosage level prescribed to a patient, by a physician, into a host system (Denny; Abstract). Such a method/system would have further provided for the retrieval of the prescribed drug and dosage level information from the host system, by a pharmacist, for the purpose of filling the prescription for the patient (Denny; Abstract). Additionally, such a system/method would have enabled the pharmacist to enter information indicating that the prescription had been filled into the host system for the review of the prescribing physician (Denny; paragraphs [0035] [0041] [0053]). Lastly, such a method would have been enabled by a integrated system in which the payor, PBM, pharmacy, and provider access and manipulate the same information, including prescribed drug, quantity/dosage, refills, cost, and reimbursement rules (Borsand et al.; paragraphs [0040] [0064]). The motivation to combine the teachings would have been to enable a provider to monitor the filling of a prescription such that the prescription can be cancelled in the event of fraud, abuse, or mistakes, such as a pharmacist filling a prescription at half strength but twice the volume and cost (Borsand et al.; paragraphs [0005] [0120]).

As per claim 22, Denny discloses a method further comprising comparing the different medication brand or dosage of the unfilled prescription with the filled and different medication brand or dosage and generating a warning of the different medical brand or dosage (Denny; paragraph [0053]).

As per claim 27, Denny discloses a method comprising registering medical service professionals authorized to access a database associated with the processing center (Denny; paragraphs [0027] [0029] [0043] [0047]).

As per claim 28, Denny discloses a method wherein entering the filled medication generates a warning signal to the prescribing physician or medical service provider (Denny; paragraph [0053]).

Regarding claim 28, Denny discloses a check for prescription data validity and subsequent messaging to the physician, Denny fail to explicitly recite that the data check specifically check the contents of the filled prescription, i.e., dosage and brand.

However, as is evidenced by Borsand et al., it is well known in the prescription fulfillment art for the pharmacist to record or enter into a database, information regarding the specifics of a filled prescription including cost, drug type, and quantity administered to the patient. Accordingly, Borsand et al. teach a method wherein said filled prescription data includes "filled and different"

information (Borsand et al.; paragraphs [0005] [0040] [0056] [0064] [0086] [0118] \*see electronic representation of filled prescription).

As per claim 29, while Denny discloses a warning mechanism, Denny fails to specifically indicate that the warnings are sent to an insurance company.

However, Borsand et al. disclose a method wherein entering the filled prescription medication generates a warning signal to an insurance company (Borsand et al.; paragraphs [0005] [0034] [0120]-[0122] and Fig. 11).

NOTE: Borsand et al. provide a system and method that supports tracking pharmaceutical, prescription, and related information throughout the life cycle of the pharmaceutical or prescription (Borsand et al.; paragraph [0034]). Borsand et al. further specify that information tracking can be in a proactive and real-time manner (Borsand et al.; paragraph [0034]). Borsand et al. further teach that a purpose of proactive and real-time tracking of information is to identify instances of fraud or error, such as a pharmacist filling a prescription at half strength and half strength and twice the volume and cost (Borsand et al.; paragraph [0005]). Examiner's interpretation of the above noted teachings of Borsand et al. constitute a "warning" mechanism indicating that a pharmacist has failed to fill a prescription properly.

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As per claim 30, Denny discloses a method wherein the processing center is accessed by the physician, medical service provider or pharmacist by a telecommunications link (Denny; paragraphs [0023] [0038]).

Regarding claims 22 and 27-30, the conclusions of obviousness and statements of motivation as discussed with regard to claim 21 above are applicable to claims 22 and 27-30 and are herein incorporated by reference.

Claims 31-32 and 37-40 substantially repeat the subject matter presented in method claims 21-22 and 27-30 system form. Accordingly, claims 31-32 and 37-40 are rejected as obvious in consideration of Denny in view of Borsand et al. for the reasons, conclusions of obviousness, and statements motivation as discussed above with respect to claims 21-22 and 27-30.

[2] Claims 23-26 and 33-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Denny and Borsand et al. as applied to claims 1 and 12 above, and further in view of Keresman, III et al. (United States Patent Application Publication #2001/0047281).

Regarding claims 23-26, while Denny teaches authenticating and identifying provider and pharmacist systems accessing the host system (Denny; paragraph [0043]), Denny fails to specifically teach biometric identification as part of the security protocol. Borsand et al. fail to disclose biometric authentication.

However, as evidenced by Keresman, III et al., the use of biometric identification of registered doctors, pharmacies, and other participants is well known in the prescription drug fulfillment art (Keresman III et al.; paragraphs [0008] [0009] [0015] [0050] [0056]).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teachings of Denny and Borsand et al., as applied to claim 1 and 12 above, with those of Keresman, III et al. with the intention of determining that the requesting system is a valid system by using password protection or other security methods known in the art (Denny; paragraph [0043]). The motivation to combine the teachings would have been to employ a well-known security protocol to provide a suitable degree of security, which prevents unauthorized access to a patient's confidential medical and pharmaceutical records (Keresman, III et al.; paragraph [0004]).

Claims 33-36 substantially repeat the subject matter presented in method claims 23-26 in system form. Accordingly, claims 33-36 are rejected as obvious in consideration of Denny in view of Borsand et al. for the reasons, conclusions of obviousness, and statements motivation as discussed above with respect to claims 23-26.

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(10) Response to Argument

In the Appeal Brief filed 11 October 2010, Appellant makes the following arguments:

(A) The Denny Reference is not Prior Art.

(B) Borsand fails to disclose "...entering filled and different medication brand or dosage into

the processing center in fulfillment of prescribed prescription..."

(C) Borsand fails to disclose a processing center that "accepts filled prescription information

through the network from the pharmacist in fulfillment of the prescribed information but that

differs in at least one respect from the medication brand or dosage of the prescribed prescription

information...".

Examiner will address the Appellant's arguments as presented above.

**Argument (A):** 

In response to Appellant's argument that Denny is not valid prior art against the instant

applications because Denny was filed November 25, 2003, which is after the filing date of the

instant application filed 1 March, 2002, Examiner respectfully disagrees and notes that the

effective filing date of Denny is 21 September 1999. Specifically, Denny is a continuation of

U.S. application # 10/158,259, filed May 29, 2002, now U.S. Patent #6,687,676, which is a continuation of application No. 09/400,498, filed on 21 September 1999, now abandoned. Accordingly, the effective filing date of Denny is 21 September 1999 and not November 25, 2003, as Appellant contends. While Denny fails to qualify under references fail to qualify as prior art under 35 U.S.C. 102(a) or (b), the reference does qualify as prior art under 35 U.S.C. 102(e), and is therefore appropriately applied under 35 U.S.C. 103(a).

#### **Arguments (B) and (C):**

In response to Appellant's arguments B and C that the Borsand reference fails to disclose "...entering filled and different medication brand or dosage into the processing center in fulfillment of prescribed prescription..." and similarly a processing center that "accepts filled prescription information through the network from the pharmacist in fulfillment of the prescribed information but that differs in at least one respect from the medication brand or dosage of the prescribed prescription information...", Examiner respectfully disagrees.

In response, Examiner initially notes that the rejection of the subject claim/limitation is based on the combined teachings Denny in view of Borsand. Examiner secondarily notes that the functions conveyed by these limitations have been previously decided on in the previous decision of the BPAI issued 2 September 2009. In particular, Examiner directs the BPAI's attention to the findings of fact as determined in the previous appeal.

In further response, while Denny provides for the pharmacist inputting information representative or indicative of a prescription to be filled (Denny; paragraph [0035]) and subsequently provides for the pharmacist inputting a code indicating that a prescription has been filled into the host system (Denny; paragraph [0041]), Denny fails to specifically indicate that the pharmacist enters filled prescription data that that "...differs in at least one respect from the medication brand or dosage of the prescribed prescription information...".

However, as is evidenced by Borsand et al., it is well known in the prescription fulfillment art for the pharmacist to record or enter into a database (i.e., a processing center), information regarding the specifics of a filled prescription including cost, drug type, and quantity administered to the patient. Accordingly, Borsand et al. teach a method wherein said filled prescription data "...differs in at least one respect from the medication brand or dosage of the prescribed prescription information..." (Borsand et al.; paragraphs [0005] [0040] [0056] [0064] [0086] [0118]).

More specifically, Borsand et al. disclose the electronic representation of a filled prescription is generated in a substantially simultaneous manner with the filling of the prescription and the distribution of the prescribed pharmaceutical (Borsand et al.; paragraph [0084]). Borsand et al. additionally disclose that during prescription fulfillment at the pharmacy, the prescription is reevaluated in terms of reimbursement rules and medical appropriateness and that if for any appropriate business or medical reason the filling of a prescription should not occur, the pharmacist can cancel or potentially even modify the prescription as appropriate (Borsand et al.;

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paragraph [0087]). Borsand et al. further disclose that the pharmaceutical type and quantity are entered into the system as a matter of protocol during the generation of the prescription by a physician (Borsand et al.; paragraph [0064]). While Borsand et al. fail to redundantly consider the entry of quantity and type by the pharmacist during an "appropriate" modification of the prescription, Examiner submits that it is reasonable to assume these steps are repeated by the pharmacist making changes to the prescription. Examiner further submits that the noted assumption is justified in view of the objectives of the Borsand et al., which include the desire to "prevent a pharmacist from filling a prescription at half the strength but twice the volume and cost" (Borsand et al.; paragraphs [0005] [0082]). In view of the above noted teachings, Examiner submits that the collective teachings of Borsand et al. include the entry of the pharmaceutical type and quantity actually dispensed by the pharmacist, i.e., "analyzing changes in the prescription that are made by the pharmacist.

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(11) Related Proceeding(s) Appendix

Copies of the court or Board decision(s) identified in the Related Appeals and

Interferences section of this examiner's answer are provided in the attached documents and as an

Appendix included in Appellant's Brief filed 11 October 2010.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/R. David Rines/

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